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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/006,999	01/14/1998	CLIVE J. SHIFF	PMS241460	4395

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EXAMINER

CYGAN, MICHAEL T

ART UNIT	PAPER NUMBER
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2856

DATE MAILED: 03/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/006,999

Applicant(s)

SHIFF ET AL.

Examiner

Michael Cygan

Art Unit

2856

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,6-8 and 10-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,6-8 and 10-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Mudambi (Proceed. 26th Conf. Great Lakes Res., May 1983). Mudambi discloses a continuous flow apparatus comprising a continuous flow centrifuge and a XAD-8 filtration column. XAD-8 is a particulate material composed of micron-sized polyaromatic particles, disclosed here to be packed into a column which restricts large-diameter molecules from passing through.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 4, 6-8, and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitmore (Wat. Sci. Tech. 1993) in view of Olsson (US 5,019,497). Whitmore discloses the claimed invention, a continuous flow centrifuge and method for using the centrifuge to recover cryptosporidium from water (pages 69 and 72), except for the use of a particulate column in the centrifuge apparatus. Olsson teaches the use of a particulate column (Sephadex) mounted in a centrifuge tube to catch the flow through containing a desired sample material (column 7, lines 10-23). It would have been obvious to use a particulate column as taught by Olsson in the invention taught by Whitmore to filter the desired material (cryptosporidium) from water, since this would eliminate the tedious deposit transferal steps (involving scraping material from the centrifuge and rinsing with water). Further motivation is provided by Whitmore in the abstract, which states that "continuous flow centrifuges tested were not shown to be capable of yielding satisfactory recoveries, although it is considered more refined machines currently available may warrant investigation"; thus pointing for the need for an improved centrifugation recovery apparatus.

With respect to the choice of particulate material for cryptosporidium, Whitmore teaches that sand can be used as a particulate filter which retains cryptosporidium (page 71). It would have been obvious to use sand as taught by Whitmore as the particulate filter material as taught by

Whitmore in view of Olsson, since sand is shown to retain the desired material (cryptosporidium).

With respect to claims 10-11, the claimed invention is taught by Whitmore in view of Olsson as stated above, except for the size ranges stated. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use sand of 200-50 micrometers or 120-50 micrometers, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum of workable ranges involves only routine skill in the art. See *In re Aller*, 105 USPQ 233. Additionally, in *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

3. Claims 1, 4, 6-8, and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borschardt (US 5,846,439) in view of Leu (US 5,866,071). Borschardt teaches a continuous flow centrifuge (column 3, lines 64-67) used to filter *Cryptosporidium* oocysts from a solution (column 4, lines 37-55).

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With respect to claim 1, Borschardt teaches the claimed invention except for the use of a particulate filtration column. Leu teaches the use of a particulate filtration column in a centrifuge (figures 4a, 4b, 4c; column 2, lines 62-65; column 3, lines 4-9 and 27-40) to enhance the separation abilities of the centrifuge (column 1, lines 13-23). In the apparatus of Leu. In the apparatus of Leu, a column is packed with finely divided dextran particles (column 4, lines 35-53). The particulate material in the column consists of several different zones (d1-d5) of dextran concentration. When sample material (P0), such as cellular solutions (column 4, lines 35-36) to be filtered is placed in the column, operation of the centrifuge forces the sample material to be forced through the dextran particulate material. The sample material (layer P0 in Figure 4a) is filtered into its constituent parts (layers P1,P2,P3 in Figure 4b) through dextran layers (d2-d4) by the interaction of the sample with the particulate material (column 4, lines 46-50).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the column of Leu in the continuous flow centrifuge of Borschardt since Leu states that the addition of a media column increases the separation ability of the centrifugation; during centrifugation, analytes are separated into different media according to their densities (column 3, lines 39-40). Without such a media column, centrifugation results in a pellet consisting not only of the desired cellular material, but also containing other fragmentary material which is not desired.

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With respect to claims 4 and 12, Borchardt in view of Leu teaches the claimed invention as stated above except for the use of glass or sand particulate material. Borchardt discloses that it is known in the art to use sand columns to filter oocysts from water in flow systems (column 2, lines 17-31). It would be obvious to use sand columns in the centrifuge of Borschardt in replacement of the media of Leu, as sand columns are known to filter oocysts.

With respect to claims 6-8, Borschardt teaches that it is known in the art to perform microorganism, cryptosporidium in particular, concentration in a fluid stream of a continuous flow centrifuge (column 2, lines 41-42).

With respect to claims 10-11, the claimed invention is taught by Borschardt in view of Leu as stated above, except for the size ranges stated. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use sand of 200-50 micrometers or 120-50 micrometers, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum of workable ranges involves only routine skill in the art. See *In re Aller*, 105 USPQ 233. Additionally, in *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Wilson (US 3,583,627) discloses a continuous flow centrifuge apparatus having within semipermeable membrane filters to remove cellular material from large volumes of liquid flowing continuously from a reservoir or similar source.
5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Response to Arguments

6. Applicant's arguments filed 04 March 2003 have been fully considered but they are not persuasive.
7. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "within the centrifuge", "larger particulate matter", "simple and inexpensive", "cost") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).
8. In response to applicant's argument that the process of adsorption is somehow different than filtration, the examiner once again presents the definition of "filtration":

Filtration: the process of passing through or as if through a filter. Filter: a porous article or mass (as of paper or sand) through which a gas or liquid is passed to separate out matter in suspension.

Clearly, then, passing a fluid through an adsorbent medium such as XAD-8 which restricts large-molecule particles from passing through qualifies as a filtration. Furthermore, applicant's representative's definition of XAD-8 as merely an "adsorbent" is inadequate, since a packed column of XAD-8 as presented in the Mudambi reference forms a filter which allows particles having a certain size or smaller to pass while restricting the passage of larger molecules.

9. The examiner notes for the record that applicant's representative has acquiesced to the examiner's assertion that the dextran column taught by Leu is in fact a filtration medium (see page 2 of applicant's response dated 04 March 2003).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Cygan whose telephone number is 703-305-0846. The examiner can normally be reached on 8:30-6 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams can be reached on 703-305-4705. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7722 for regular communications and 703-308-7722 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0956.

MTL

Michael Cygan, Ph.D.
March 11, 2003

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